

Notice of Allowability

Application No.

10/761,615

Applicant(s)

YAYON ET AL

Examiner

Lora E. Barnhart

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9-19.
2. ☒ The allowed claim(s) is/are 1-53.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Allan Fanucci on 10/31/05.

The application has been amended as follows:

In claim 7, line 5, "PEG" has been replaced with - - - polyethylene glycol - - -.

In claim 10, line 2, after the word "hepatocytes," insert the word - - - and - - -.

In claim 21, line 5, "PEG" has been replaced with - - - polyethylene glycol - - -.

In claim 30, line 5, "PEG" has been replaced with - - - polyethylene glycol - - -.

In claim 33, line 2, after the word "hepatocytes," insert the word - - - and - - -.

In claim 41, line 5, "PEG" has been replaced with - - - polyethylene glycol - - -.

In claim 44, line 2, after the word "hepatocytes," insert the word - - - and - - -.

In claim 50, line 1, the words "for an implant" have been deleted.

Claims 54-56 are cancelled.

Reasons for Allowance

Previously withdrawn claims 14-49 are rejoined to allowable Group I in compliance with *in re Ochiai* practice. The allowed claims are 1-53.

The claimed invention is distinguished over the Seelich et al. reference, which is the closest prior art, because the matrix of Seelich et al. has a residual moisture of

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approximately 15%. Applicant has added a limitation to the independent claims that the matrix must be elastic and has correctly pointed out that Seelich et al. teach that fibrin matrices with less than 3% residual moisture are not elastic (Seelich et al., column 8, lines 35-46 and column 1, lines 64-67). A thorough search of both patent and non-patent databases failed to yield any elastic fibrin matrices with less than 3% residual moisture. The fibrin matrix of Redl et al. (1983, GB 2,102,811; reference N) comprises an anti-fibrinolytic agent (for example, tranexamic acid) and is fully lyophilized (Examples 1-4) but cannot be considered elastic (page 3, lines 16-19). Wikipedia.com (reference U) is cited as evidence that the elasticity of the matrices of Redl et al. (*i.e.*, Young's modulus of 426 or 1150, depending on components) is comparable to tungsten metal or diamond, respectively (page 3), which cannot reasonably be considered elastic. The instantly described matrices, however, are deformable and pliable (specification as filed, page 26, line 24, through page 27, line 18). As such, the selection of the amount of residual moisture would not have been a matter of routine optimization if the matrix were required to be elastic.

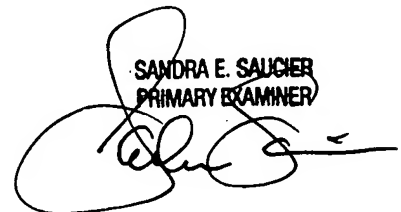
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart



SANDRA E. SAUCHER
PRIMARY EXAMINER